Department of Energy
Environmental Management
Policies and Procedures

Review of EM Safety Basis Documentation

EM –7.3
Revision 0

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REVISION LOG

Revision Number	Description of Revision	Approval Date
0	Initial Issue (replaces EM H&S-01 Rev. 2)	September 11, 2002

TABLE OF CONTENTS

LIST OF ACRONYMS

AA	Authorization Agreement
AMEM	Assistant Manager for Environmental Management
AMESH	Assistant Manager for Environment, Safety, Health and Emergency Management
ASA	Auditable Safety Analysis
BIO	Basis for Interim Operations
COR	Contracting Officer's Representative
DOE	U.S. Department of Energy
DSA	Documented Safety Analysis
EM	Environmental Management
FHCD	Final Hazard Categorization Document
HAD	Hazard Assessment Document
HC	Hazard Category
ISMS	Integrated Safety Management System
JCO	Justification for Continued Operations
NSD	Nuclear Safety Division
ORO	Oak Ridge Operations
PISA	Potential Inadequacy in the Safety Analysis
QA	Quality Assurance
SAR	Safety Analysis Report
SB	Safety Basis
SER	Safety Evaluation Report
TSR	Technical Safety Requirements
USQ	Unreviewed Safety Question

1.0 PURPOSE

The purpose of this procedure is to document the process that the U.S. Department of Energy (DOE) Oak Ridge Operations Office (ORO) Environmental Management (EM) program shall utilize to review and approve Safety Basis (SB) documents and to track the status of SB documents for new and existing Hazard Category 1, 2, and 3 nuclear facilities, including major modifications. SB documents covered under this procedure include Documented Safety Analyses (DSAs), Safety Analysis Reports (SARs), Justification for Continued Operations (JCOs), Basis for Interim Operations (BIOs), Technical Safety Requirements (TSRs), Unreviewed Safety Question (USQ) evaluations, Hazard Assessment Documents (HADs), Final Hazard Categorization Documents (FHCDs), and other related safety documents for EM facilities and operations. Requirements under this procedure are derived from ORO O 420, Chapter XIII, *Safety Basis Document Review System* (Reference 3.1.3), which correlates to Title 10 Code of Federal Regulations (CFR) Part 830, *Nuclear Safety Management*, Subpart B (Reference 3.1.1).

2.0 SCOPE

This procedure applies to EM personnel and support staff who participate in the review, approval and tracking of EM safety basis documentation.

NOTE: This procedure supercedes EM H&S-01 Rev. 2, *Safety Document Review Procedure*.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 Title 10, Code of Federal Regulations, Part 830, *Nuclear Safety Management*

3.1.2 DOE-ORO M 411.1-1D, *Manual of Safety Management Functions, Responsibilities, and Authorities, Level II, for Oak Ridge Operations* (October 31, 2000)

3.1.3 DOE-ORO O 420, Facility Authorization, Chapter XIII, *Safety Basis Document Review System*

3.1.4 DOE-ORO O 420, Facility Authorization, Chapter XI, *Authorization Agreements*

3.1.5 DOE-ORO O 420, Facility Authorization, Chapter XIV, *Delegation of Approval Authority for Safety Basis Documents*

3.1.6 DOE O 425.1B, *Startup and Restart of Nuclear Facilities*

3.1.7 DOE-STD-1027-92, *Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports*

3.1.8 DOE-STD-1104-96, *Review and Approval of Nonreactor Nuclear Facility Safety Analysis Reports*

3.1.9 DOE-STD-1120-98, *Integration of Environment, Safety, and Health into Facility Disposition Activities*

3.1.10 DOE-STD-3009-94, *Preparation Guide for U.S. Department of Energy Non-reactor Nuclear Facility Safety Analysis Reports*

3.1.11 DOE-STD-3011-94, *Guidance for Preparation of DOE 5480.22 (TSR) and DOE 5480.23 (SAR) Implementation Plans*

3.1.12 DOE G 421.1-2, *Implementation Guide for Use in Developing Documented Safety Analyses to Meet Subpart B of 10 CFR 830*

3.1.13 DOE G 423.1-1, *Implementation Guide for Use in Developing Technical Safety Requirements*

3.1.14 DOE G 424.1-1, *Implementation Guide for Use in Addressing Unreviewed Safety Question Requirements*

3.1.15 ORO-AMEM, February 10, 2000, EM Procedure No. EM-4.2, *Facility Walkthroughs*, DOE-ORO, Oak Ridge, TN

3.1.16 ORO-AMESH, June 2002, AMESH Procedure No. AMESH-SB-1, *Review of Safety Basis Documentation*.

3.1.17 DOE Memorandum from J. Roberson, EM-1, to the ORO Manager; *Delegation of Authority*, November 20, 2001.

3.1.18 DOE-ORO Memorandum from R. C. Sleeman, EM-92 COR, to P. F. Clay, Bechtel Jacobs Co.; *Format and Expectations for Justification for Continued Operations*, November 7, 2001.

3.1.19 DOE-ORO Memorandum from L. Fritz, EM-90 COR, to P. F. Clay, Bechtel Jacobs Co.; *Safety Basis Implementation Guidance*, June 21, 2002.

3.2 DEFINITIONS

Note: The source of each definition, where available, is indicated in parentheses.

3.2.1 Approval Authority: The person or organization that has been granted authority by the Cognizant Secretarial Officer to approve safety basis documents prepared in accordance with requirements in 10 CFR 830, Subpart B. (Reference 3.1.5)

3.2.2 Authorization Agreement (AA): A documented agreement between DOE and the contractor that defines the authorization basis for a defined scope of work. The authorization agreement contains key terms and conditions (controls and commitments) under which the contractor is authorized to perform work. [Any changes to these terms and conditions require DOE approval. The safety basis is a subset of the authorization agreement.] (Reference 3.1.4)

3.2.3 Documented Safety Analysis (DSA): A documented analysis of the extent to which a facility can be operated safely with respect to workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety. (Reference 3.1.1, 3.1.3)

3.2.4 Final Hazard Categorization Document (FHCD): A document which establishes, through Hazard Analysis, the final hazard category of a facility. DOE-STD-1027-92 provides guidance on determining the final hazard category of a facility. The FHCD for a given facility may range from a brief Hazard Assessment Document (HAD) to a formal DSA document such as an Auditable Safety Analysis (ASA) or Safety Analysis Report (SAR).

3.2.5 Graded Approach: The process for ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with (1) the relative importance to safety, safeguards and security, (2) the magnitude of any hazard(s) involved, (3) the life cycle stage of the facility, (4) the programmatic mission of the facility, (5) the particular characteristics of the facility, (6) the relative importance of the radiological and nonradiological hazards, and (7) any other relevant factor. (Reference 3.1.1, 3.1.3)

3.2.6 Hazard Categorization: Evaluation of the consequences of unmitigated releases to classify DOE nuclear facilities or operations into the following hazard categories:

- Hazard Category 1: The hazard analysis shows the potential for significant off-site consequences.
- Hazard Category 2: The hazard analysis shows the potential for significant on-site consequences.
- Hazard Category 3: The hazard analysis shows the potential for only significant localized consequences.

[Note: DOE-STD-1027-92 provides guidance and radiological threshold values for determining a facility's Hazard Category.] (Reference 3.1.1, 3.1.3)

3.2.7 Hazard Controls: Measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including: (1) physical, design, structural, and engineering features; (2) safety structures, systems, and components; (3) safety management programs; (4) technical safety requirements; and (5) other controls necessary to provide adequate protection from hazards. (Reference 3.1.1)

3.2.8 Justification for Continued Operations (JCO): A document requesting DOE approval of operations on a temporary basis after identifying a PISA, USQ, or other condition where current requirements of the safety basis cannot be fully met or do not address the identified concern. (Reference 3.1.3)

3.2.9 Lead Reviewer (SER Preparer): The individual selected to review a safety basis document and, if applicable, direct the review team. (Reference 3.1.3)

3.2.10 Potential Inadequacy in the Safety Analysis (PISA): An issue or problem for which the extent of impact on the safety analysis is not known, but for which there exists sufficient

possibility that, after further evaluation, the safety analysis supporting the Safety Basis will be found inadequate, or that the margin of safety will be found reduced. (Reference 3.1.3)

3.2.11 Safety Basis (SB): The documented safety analysis (DSA) and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment. (Reference 3.1.1)

3.2.12 Safety Evaluation Report: The report prepared by DOE to document: (1) the sufficiency of the documented safety analysis for a hazard category 1, 2, or 3 DOE nuclear facility; (2) the extent to which a contractor has satisfied the requirements of 10 CFR 830 Subpart B; and (3) the basis for approval by DOE of the safety basis for the facility, including any conditions for approval. (Reference 3.1.1)

3.2.13 Technical Reviewer: A reviewer assigned to perform a peer review of the comprehensiveness and technical adequacy of the safety basis document and associated SER. This may be accomplished through the Assistant Manager for Environment, Safety and Health (AMESH) independent review function. (Reference 3.1.3)

3.2.14 Technical Safety Requirements (TSRs): The limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and hazards identified in the documented safety analysis for the facility: safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix. [TSRs were formerly known as Operational Safety Requirements for nonreactor nuclear facilities and Technical Specifications for reactor facilities.] (Reference 3.1.1, 3.1.3)

3.2.15 Unreviewed Safety Question (USQ): A situation [either proposed as a future activity or discovered to already exist] where: (1) The probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analysis could be increased; (2) The possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analysis could be created; (3) A margin of safety could be reduced; or (4) The documented safety analyses may not be bounding or may be otherwise inadequate [e.g., due to a discrepant as-found condition, an operational event or incident, or discovery of new information, including errors in the analysis]. (Reference 3.1.1, 3.1.3)

3.2.16 Unreviewed Safety Question (USQ) Process: The mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting unreviewed safety questions to DOE, and obtaining approval from DOE prior to taking any action that involves an unreviewed safety question. (Reference 3.1.1)

4.0 RESPONSIBILITIES

4.1 Assistant Manager for Environmental Management (AMEM)

4.1.1 Ensures that contractors develop SB documents in accordance with 10 CFR 830 and established DOE requirements and guidelines.

4.1.2 Ensures that submitted SB documents are reviewed for technical accuracy and compliance with DOE requirements and guidelines, and that any resulting comments are resolved.

4.1.3 Ensures that Safety Evaluation Reports (SERs) are generated, properly reviewed and approved.

4.1.4 Obtains approval of the SB document (i.e., direct approval for categories of facilities and/or types of documents for which approval authority has been delegated to the AMEM, or the recommendation for approval by the designated approval authority for other categories).

4.1.5 Ensures that contractors implement SB documents, update affected Authorization Agreements, and update SB document configuration control list.

4.1.6 Ensures that implementation issues are identified and corrected in a timely manner.

4.2 Contracting Officer's Representative (COR)

4.2.1 Serves as the official point-of-contact between the contractor and DOE for submittal of SB documents, DOE review comments and contractor responses, and SERs.

4.2.2 Upon receipt of a SB document submittal from the contractor, ensures that it is logged into the tracking system and assigns the SB document to the responsible manager and the EM Safety Basis Technical Lead for review.

4.2.3 Provides advisory guidance to contractors concerning SB issues. (Includes consultation with the AMESH-Nuclear Safety Division (NSD) on guidance provided to contractors related to issues not previously addressed in DOE requirements or guidance documents.)

4.3 EM Safety Basis Technical Lead

4.3.1 Serves as primary EM technical point-of-contact and general subject matter expert (SME) for SB documents.

4.3.2 Leads the planning, coordination, and review activities that support the preparation of SB documents for the EM program mission. Selects qualified Lead Reviewer and Technical Reviewer for SB documents.

4.3.3 Provides oversight for the USQ process.

4.3.4 Ensures that a tracking system is maintained of the EM SB documents and Authorization Agreements, along with an archive of approved SB documents and Authorization Agreements.

4.3.5 Ensures that the contractor transmits a quarterly report that provides a schedule of projected submittals of new and revised SB documents with a minimum one year planning horizon.

4.3.6 Provides advisory guidance to contractors concerning SB issues. Interfaces with EM, NSD, and other personnel as necessary to resolve SB issues.

4.3.7 Ensures that independent assessments are regularly scheduled and conducted (normally by the EM ES&H Oversight Team Leader) to assure the adequacy of SB document implementation, and to assure compliance with SB document process requirements, including an appraisal of contractor technical competency, adequacy of safety management programs, and review of internal DOE EM procedure implementation.

4.4 Lead Reviewer

4.4.1 Determines, after receiving input from the responsible manager, that an SB document received from the contractor is of sufficient quality to be reviewed in depth for DOE approval.

4.4.2 Reviews SB documents for technical accuracy and compliance with DOE requirements and guidelines and/or arranges and coordinates the review with other subject matter experts and the responsible managers. Determines review schedule through discussions with the responsible managers and SME's.

4.4.3 Resolves DOE issues and comments generated by DOE reviews.

4.4.4 Obtains unique SER document number from AMESH-NSD.

4.4.5 Prepares the SER for the signature of the approval authority.

4.5 Group Leader/Site Manager

4.5.1 Ensures the implementation of this procedure at EM facilities and operations under his/her purview, and ensures that an approved safety basis is in place for these facilities.

4.5.2 Ensures that new or revised SB documents are prepared as required by DOE requirements and guidelines in a schedule supportive of project needs.

4.5.3 Upon receipt of a new or revised SB document from the COR, ensures that the document is assigned to appropriate staff for preliminary review to determine whether the document is of sufficient quality to be reviewed in depth for DOE approval, and provides recommendations to the SB Technical Lead.

4.5.4 Following successful review, recommends SB documents to the AMEM for approval.

4.5.5 Ensures that approved SB documents are implemented in the field at facilities for which he/she has responsibility.

4.5.6 Ensures that a verification review of contractor implementation of a new or revised SB is performed, within 60 days of completion of implementation by the contractor, to ensure that SB requirements have been properly implemented and that personnel are aware of the changes as appropriate. Verification may be performed in phases as implementation milestones are completed by the contractor.

4.6 EM ES&H Support Team Leader

4.6.1 Provides SME's for review of SB documents as requested by the Lead Reviewer.

4.7 EM ES&H Oversight Team Leader

4.7.1 At the request of the SB Technical Lead, schedules and conducts technical assessments of SB document implementation and of processes for preparation, review and change control of SB documents.

4.7.2 Tracks all issues and deficiencies associated with implementation of this procedure, ensuring that any required corrective actions are verified.

4.8 Facility Representative

4.8.1 Participates in the review of new or revised SB documents, providing input to the responsible manager, Lead Reviewer, and other reviews.

4.8.2 Conducts walk-through of the subject facility/activity, and facilitates walk-through by reviewers, as required (see Reference 3.1.15).

4.8.3 As a part of day-to-day operational safety oversight of assigned facilities, maintains a thorough awareness of the applicable safety basis.

5.0 PROCEDURE

5.1 Safety Basis Document Review and Approval Process

Note: Prior to the contractor beginning work on a new SB document or major revision, it is recommended and expected that a meeting be held between the contractor and DOE (including the responsible manager and SB Technical Lead) to discuss the proposed development and approval strategy. This includes the scope of the submittal, methods being chosen to demonstrate compliance, the degree of backfit analysis/equipment replacement expected, and the process of implementation. The agreements between DOE and the contractor from this meeting should be documented, approved by DOE and contractor management, and maintained current as the guiding direction for both the DOE and contractor staffs.

Note: Attachment A provides a flowchart of the review and approval process described in this Section. Attachment B provides an overview of the development process for DSA documents. Attachment C provides guidance on approval requirements for radiological (below Hazard Category 3 nuclear facilities).

5.1.1 All SB documents to be reviewed by EM for approval purposes shall be formally transmitted from the contractor to the COR.

5.1.2 Upon receipt of a new or revised SB document, the COR shall:

5.1.2.1 Log the document into the EM SB document tracking system, with a due date for the DOE approval decision normally not to exceed 90 days from the date of receipt (for SB documents where ORO has approval authority) and notify the AMEM in accordance with the requirements of Reference 3.1.3. If the 90-day due date is determined not to be adequate, the AMEM must obtain approval from the ORO Deputy Manager for Operations for an alternative schedule per Reference 3.1.3.

Note: Data tracked for each SB document in this system shall include the document name, approval status, name and location of affected facility(ies), schedule of pending and projected revision/update actions, corrective actions, and other pertinent information.

5.1.2.2 Transmit the SB document to the responsible manager and the SB Technical Lead for review.

5.1.3 The responsible manager shall assign the document to appropriate staff for preliminary review to determine whether the document is of sufficient quality to be reviewed in depth for DOE approval, and provide a recommendation to the SB Technical Lead. If determined to be suitable for formal review, the SB Technical Lead will initiate the formal review process; otherwise, he/she will return the document to the COR for return to the contractor, along with a written description of the EM basis for rejection.

5.1.4 The SB Technical Lead shall identify a Lead Reviewer and a Technical Reviewer (peer verification) for the SB document. The Lead Reviewer and Technical Reviewer must be qualified under the DOE Technical Qualification Program. Alternate qualifications based on knowledge and experience, or "under the supervision of a qualified individual" may be considered if approved by the AMEM. A separate Technical Reviewer is not required for team reviews, since multiple reviewers are already engaged in the process.

Note: The Lead Reviewer and/or Technical Reviewer may be affiliated with DOE organizations other than EM (e.g., NSD) or contractors.

5.1.5 The Lead Reviewer shall perform the following:

5.1.5.1 Evaluate the scope of the review effort to determine if additional resources are required and if a review plan is warranted. Use of a review plan and a multi-disciplinary review team are highly recommended for initial issuance of SB documents, commensurate with the level of complexity and hazards of the facility (graded approach). Identify appropriate reviewers, including the responsible Facility Representative, responsible manager, subject matter experts (SMEs), and other staff, as necessary, and request their participation through the appropriate management chain of command. Ensure that copies of the SB

document are distributed to all reviewers. A walk-through of the affected facility by all reviewers is recommended, where practicable.

Note: Reviewers and SMEs may include non-EM personnel and contractors.

5.1.5.2 Review the document to ensure its technical adequacy and compliance with DOE requirements and guidelines. Coordinate input from all designated reviewers into a single document review record. [See Reference 3.1.16 for review guidelines.]

5.1.5.3 Promptly and formally communicate comments/issues generated during the review process to the contractor through the COR. A comment resolution matrix similar to that found in Reference 3.1.16 should be used. In the case where a potential unreviewed safety question (USQ) is discovered during the review, the Lead Reviewer shall notify contractor facility management and the COR immediately to ensure that the contractor takes appropriate action to place or maintain the facility in a safe condition. (See Section 5.2 for additional requirements for USQs.)

5.1.5.4 If the Lead Reviewer determines that DOE will be unable to approve the submitted document without substantial clarification and/or numerous conditions for approval, he/she will make a recommendation to the SB Technical Lead to return the document to the COR to formally transmit the document back to the contractor with the basis of DOE's disapproval clearly documented.

Note: This step may be omitted in cases where the contractor recognizes the need for a modification to the document based on DOE comments and resubmits a corrected document without receiving an official rejection letter.

5.1.5.5 If the Lead Reviewer can recommend approval of the submitted document, he/she shall prepare a Safety Evaluation Report (SER), or coordinate the review team's input on the SER, to document the basis of DOE approval for SB documents for new, existing, and/or major modifications for Hazard Category 1, 2, and 3 nuclear facilities and for revisions/ updates to compliant SB documents. Note: A supplement to an existing SER may be sufficient for an annual update.

5.1.5.6 The SER must be prepared and issued in accordance with References 3.1.8 and 3.1.16.

5.1.5.7 The Lead Reviewer should ensure that DOE's conditions for approval in the SER constitute an appropriate and minimal essential set of conditions that is clearly stated to facilitate its implementation.

5.1.6 The Technical Reviewer shall review the SB submittal and the SER to verify that the SER is comprehensive and technically adequate. This peer verification is intended to provide a second check of the conclusions derived and identify inadvertent omissions from the SER. Comments/issues generated by the Technical Reviewer must be resolved with the Lead Reviewer or elevated through the chain of command. (This step is not required for team reviews due to the multiple reviewers already engaged in the process. This step may also be accomplished through the AMESH independent review function.)

5.1.7 A technically qualified individual must approve the SER. Normally, this will be a qualified Senior Technical Safety Manager. A single individual can perform the technical review (see 5.1.6 above) and approve the SER, if desired.

5.1.8 The Lead Reviewer shall confirm the SB approval authority as specified in Reference 3.1.5, and prepare an approval package that includes:

- A memorandum that summarizes the SB submittal, conditions for approval, exemptions/exceptions, any nonstandard compliance issues, and a recommendation for approval;
- The approved SER;
- The contractor SB submittal; and
- A concurrence correspondence form.

5.1.9 The SB Technical Lead shall concur with the approval package and forward the package to the AMEM for concurrence review.

5.1.10 The AMEM shall concur with the approval package, and forward the approval package to the AMESH for concurrence per Reference 3.1.3. For SB documents where the SER has been prepared by AMESH personnel on behalf of AMEM, no additional concurrence by the AMESH is required (AMESH concurrence will have been obtained previously), and the AMEM shall route the approval package through the chain of command to the approval authority. [Note: For SB documents where the AMEM is the approval authority, the ORO Deputy Manager for Operations will be contacted for a decision on the need for an independent check by the AMESH.]

5.1.11 The AMESH organization shall perform an independent review of the SER for SB documents where the ORO Manager is the approval authority, as well as for other SERs as specifically directed by the Deputy Manager for Operations per Reference 3.1.3. The depth of the review should be commensurate with the risk and complexity of the safety basis. The AMESH independent reviewer shall address any issues in writing to the SER lead preparer, and if the issues are not resolved promptly, the AMESH independent reviewer shall escalate them through the chain of command using the ORO dispute resolution process. The AMESH independent reviewer must document the basis for reaching his/her conclusions on the adequacy of the SER.

5.1.12 Following completion of the AMESH independent review (where necessary) and successful resolution of any comments generated, the approval package shall be routed through the chain of command to the approval authority.

5.1.13 If the SB document is approved, the COR shall transmit a formal approval letter to the contractor along with the DOE SER. The transmittal letter shall establish the DOE expectations regarding any implementation issues or the need for an implementation plan, as well as the need for any reviews required by Reference 3.1.6. Alternatively, if the SB document is rejected by the approval authority, the COR shall transmit that information to the contractor in a formal letter, with a description of the basis for rejection.

5.1.14 The SB Technical Lead shall ensure that pertinent records from the SB document approval process are archived in accordance with Section 6.0. At a minimum, these records will include the SER and documentation associated with DOE review and approval of the SB document (e.g., review comments, resolution matrices, transmittal correspondence between the contractor and DOE, independent analyses or calculations performed by or for DOE, any minority opinions).

5.1.15 The responsible manager shall perform a verification review of the SB implementation, within 60 days of completion of implementation by the contractor, to ensure that requirements have been properly implemented and that personnel are aware of the changes as appropriate. These reviews may be conducted using EM walkthrough (Reference 3.1.15) and assessment procedures, and must be documented. Verification may be performed in phases as implementation plan milestones are completed by the contractor. SB changes that are within the scope of Reference 3.1.6 may require a readiness assessment or operational readiness review in order to verify readiness for SB implementation prior before startup is authorized.

Note: All SB submittals must identify the time required for implementation following ORO approval per Reference 3.1.19. If an effective date is not specified, ORO will consider the SB to be effective immediately upon DOE approval. If the time to implement a newly approved SB exceeds 45 days or is complex, then a formal implementation plan (IP) is required. The IP shall identify the estimated cost of implementation along with major milestones. SB implementation should be of high priority and should normally be accomplished within 90 days of DOE approval. The contractor must submit for DOE approval written justification for any implementation period exceeding 90 days.

5.1.16 The responsible manager shall verify that the affected Authorization Agreement(s) are updated to reflect the new SB document.

5.1.17 The SB Technical Lead shall ensure that the controlled list of SB documents is updated to reflect the new SB document.

5.2 Unreviewed Safety Question (USQ) Review and Approval

5.2.1 Provisions of 10 CFR 830.203 require that DOE contractors must establish a process for reviewing potential unreviewed safety questions (USQs), reporting USQs to DOE, and obtaining approval from DOE prior to taking any action that involves a USQ. The contractor shall prepare a USQ determination (USQD) and safety evaluation to determine whether a proposed change or as-found condition may constitute a USQ. DOE does not approve the USQD, but must review and approve any revision to the SB documentation that may be required in response to a USQ, in accordance with the process described in Section 5.1.

5.2.2 In the event of a potentially inadequate safety analysis (PISA), the contractor is expected to take appropriate action (compensatory measures) to place or maintain the facility in a safe condition. If a PISA is declared involving EM facilities or operations, the AMEM, with the assistance of the SB Technical Lead, the cognizant Group Leader/Site Manager

and responsible subordinate managers/staff, and the Facility Representative, shall perform the following actions:

5.2.2.1 Assess the contractor's self-imposed operating restrictions, or lack thereof. If the facility or operation cannot be maintained in its current configuration without significantly increasing the risk to workers, the public, or the environment, the COR shall direct the contractor to curtail or suspend operations and/or movement of fissionable material, or to implement emergency actions or protective measures, as necessary, to place the facility or operation in a safe condition.

5.2.2.2 Monitor the contractor's activities related to the PISA and associated USQ determination for timeliness and technical adequacy. Any issues identified shall be communicated in writing by the COR to the contractor for resolution.

5.2.2.3 Determine the need and schedule for the contractor to submit a Justification for Continued Operations (JCO) to request authorization to continue essential operations prior to DOE's completion of its review of the contractor's safety evaluation, based on the need for continued essential operations, judgement of the potential risk, and the projected schedule for completing the safety evaluation. [Guidance on preparation of JCOs is provided in Reference 3.1.18.]

5.2.3 If the contractor determines that the PISA is a positive USQ (see 3.2.15), the AMEM shall ensure that review of the contractor's evaluation of the safety of the situation (including supporting safety analyses and calculations) and any associated SB document changes shall be managed according to the process described in Section 5.1. This includes review and approval of a JCO, if one is determined necessary, prior to formal submission of a permanent change to the safety basis.

5.2.4 If the contractor determines that the PISA is not a USQ, the contractor shall not be allowed to remove any restrictions associated with the PISA situation until formal approval is transmitted via the COR, following DOE's review of the contractor's safety evaluation.

5.2.5 The AMEM will determine startup or restart requirements for activities involving a positive USQ in accordance with Reference 3.1.6.

Note: A JCO may be used to authorize restart of a facility's limited essential operations from a shutdown following a USQ declaration provided that appropriate compensatory measures are in place.

5.2.6 The contractor shall submit an annual report of USQ Determinations, which shall be reviewed by the SB Technical Lead to identify any trends, anomalies, or deficiencies.

6.0 RECORDS

The following documents, which comprise the formal record of the SB review process, shall be controlled and maintained in accordance with DOE-ORO quality assurance (QA) requirements:

SERs and supporting documentation associated with DOE's review and approval of the SB document (e.g., review plan, review comments, resolution matrices, transmittal correspondence between the contractor and DOE, independent analyses or calculations performed by or for DOE, and any other pertinent documentation).

Annual summary report of USQ determinations transmitted from the contractor and any correspondence associated with the DOE determination of the adequacy of the summary report.

USQ correspondence between the contractor and DOE, and any related documentation (e.g., notifications, schedule for resolution, compensatory actions, JCOs).

7.0 ATTACHMENTS

Attachment A -	Overview of Safety Basis Review and Approval Process
Attachment B -	Overview of DSA Development Process
Attachment C -	Clarification of Approval Requirements for Safety Basis Documentation for Facilities with Radioactive Material Inventories Below Hazard Category 3 Levels

ATTACHMENT A
OVERVIEW OF SAFETY BASIS REVIEW & APPROVAL PROCESS

Contractor submits the safety basis document to AMEM-COR

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COR logs the document into tracking system & transmits the document to the responsible manager and the SB Technical Lead

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Responsible manager assigns the document to appropriate staff for preliminary review to determine if document is suitable for formal review, and makes recommendation to the SB Technical Lead. If yes, SB Technical Lead initiates formal review; otherwise, return document to COR for return to contractor.

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SB Technical Lead identifies a qualified Lead Reviewer and Technical Reviewer (Separate Technical Reviewer is not required for team reviews, since multiple reviewers are already engaged)

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Lead Reviewer (and review team, as needed) reviews the document, and coordinates resolution of any review comments. If document can be recommended for approval, Lead Reviewer prepares the SER; otherwise, Lead Reviewer returns document and review comments via the SB Technical Lead to the COR for return to contractor.

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Qualified Technical Reviewer performs peer review.

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Qualified individual (generally Senior Technical Safety Manager) approves the SER (same person can serve as qualified Technical Reviewer and approve the SER, if desired).

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Lead Reviewer determines approval authority and assembles the approval package.

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SB Technical Lead concurs on approval package and forwards it to AMEM for concurrence.

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AMEM concurs on approval package and forwards it to AMESH for concurrence (where appropriate).

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AMESH performs an independent review of the SER. Following resolution of any issues, AMESH forwards the package through the chain of command to the approval authority.

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Approval authority (e.g., ORO Manager or EM-1, consistent with current delegation of approval authority) reviews the SB package and makes approval decision.

↓

The COR formally communicates the approval status to the contractor.

↓

SB Technical Lead ensures that the appropriate records are archived and SB list is updated.

↓

Responsible manager that affected Authorization Agreement(s) are updated.

↓

Responsible manager verifies the contractor's implementation of the SB document.

ATTACHMENT B
OVERVIEW OF DSA DEVELOPMENT PROCESS

1. The contractor develops a Hazard Category determination (the initial Hazard Category and final Hazard Category both may be described in one document) and the type of Documented Safety Analysis (DSA) proposed to meet Title 10, Code of Federal Regulations, Part 830.

2. The AMEM approves the final Hazard Category in accordance with the latest delegation authority from DOE Headquarters and concurs with the DSA document type.

   Note: If delegation of approval has not been granted from Headquarters, the AMEM routes the documents to the ORO Manager for concurrence and transmittal to EM-1 for approval.

3. For (final) Hazard Category 1, 2, and 3 facilities:

   - The contractor develops the hazard analysis, accident analysis (as appropriate), and proposed controls.
   - DOE reviews and concurs with the contractor's approach.
   - The contractor develops the DSA document(s) and submits it for approval.
   - DOE approves the submitted DSA as outlined in this procedure.

   For Radiological, Chemical, and Other Industrial Facilities

   - The contractor develops and approves the DSA (see additional guidance in Attachment C).
   - DOE assesses the adequacy of the DSA as part of ORO technical oversight program.

4. The contractor implements the DSA.

5. DOE assesses the adequacy of DSA implementation.

Note: Additional guidance on development of appropriate DSAs is provided in DOE G 421.1-2, *Implementation Guide for Use in Developing Documented Safety Analyses to Meet Subpart B of 10 CFR 830*, and DOE G 421.1-2, *Implementation Guide for Use in Developing Documented Safety Analyses to Meet Subpart B of 10 CFR 830.*

ATTACHMENT C
Clarification of Approval Requirements for Safety Basis Documentation for Facilities with Radioactive Material Inventories Below Hazard Category 3 Levels

Radiological Facilities, Based Solely on Inventory: These are facilities where the radioactive material inventories fall below Hazard Category 3 levels relative to DOE-STD-1027-92, based solely on inventory levels, without resorting to analysis of the material physical form or dispersability.

- Hazard Categorization: The hazard categorization of DOE-ORO nuclear facilities with inventories of radioactive materials below Hazard Category 3 threshold levels specified in DOE-STD-1027-92 may be approved by the contractor, unless otherwise specified by ORO. The contractor will provide to DOE a list of facilities with unmitigated radiological inventories below the Hazard Category 3 thresholds. Once the initial hazard categorization is approved, no further approval of the hazard categorization is required as long as inventories stay below Hazard Category 3 levels (based solely on inventory). It is the contractor's responsibility to design and implement suitable inventory control methods to maintain acceptable inventories relative to DOE-STD-1027-92. In this case, the initial hazard categorization is all that is required.

- Safety Basis: Auditable Safety Analyses (ASAs) or other similar documents that are suitably tailored to the actual hazard are the type of documentation that is normally expected. Based on the Title10, Code of Federal Regulations, Part 830 (10 CFR 830) and the associated standards and DOE Orders, the approval level for these ASAs is the contractor organization, unless otherwise specified by ORO.

Radiological Facilities by Analysis: These are facilities where the initial hazard categorization is above the Hazard Category 3 range relative to DOE-STD-1027-92 if no credit is taken for physical form or dispersability. However, the radiological hazards in these facilities can be shown to pose sufficiently low risk to be categorized below Hazard Category 3 by analysis of the physical form and dispersability of the radioactive material (i.e., they can be categorized as "radiological" by analysis).

- Hazard Categorization: Hazard categorizations for these facilities must be approved by the DOE approval authority as delegated per Reference 3.1.5. In accordance with DOE-STD-1027-92, the characterizations must consider potential changes to physical form and dispersability under the full range of potential accident conditions that would be expected to occur within the facilities. The contractor will normally submit a Final Hazard Categorization Document (FHCD) establishing the facility hazard categorization. This will allow for an early agreement between DOE and the contractor on the final facility hazard categorization and what type of DSA will be required for the facility prior expending resources to develop the DSA. For those facilities proposed to be radiological by analysis, it will also reduce the scope of the required submittal package and DOE's review effort.

- Safety Basis: Following approval of the hazard categorization by DOE, an ASA that is suitably tailored to the actual level of hazard would be the expected type of documentation. Based on 10 CFR 830 and the associated standards and DOE Orders, the approval level for these ASAs is the contractor organization, unless otherwise specified by ORO.